MAY 1 4 2004

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

ABC Caudal and Cranial Extension Plate

December 30, 2003

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Joni Swoveland, Regulatory Affairs Assistant
800-258-1946 (phone)
610-791-6882 (fax)
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TRADE NAME: ABC Caudal and Cranial Extension Plate

COMMON NAME: Anterior Cervical Spinal Stabilization System

DEVICE CLASS: Class II

PRODUCT CODE: KWQ

CLASSIFICATION: 888.3060 - Appliance, Fixation, Spinal Intervertebral Body

REVIEW PANEL: Orthopedic

INTENDED USE

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), post-traumatic kyphosis or lordosis, tumors, and re-operation for failed previous fusions. Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

ABC extension plates MUST only be used with existing ABC plates and screws. They are NOT to be used with another manufacturers system.

DEVICE DESCRIPTION

The ABC Cervical Extension Plate is used to extend the existing anterior stabilization plate which was cleared through the Anterior Cervical Spine Plates and Screws (K974706) and Anterior Cervical Screw Spinal Fixation System (K000486).

The ABC E-Plates are exclusively used to extend an existing anterior stabilization plate on the cervical spine, which has been carried out using the ABC system. The E-Plate allows a mono-segmental or bi-segmental extension at the cranial or caudal end of the existing ABC plate.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new ABC System conforms to ASTM standard F1717, ISO standards and the Guidance for Spinal System 510(k).

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the ABC Extension is substantially equivalent to our existing Anterior Cervical Spine Plates and Screws (K974706) and Anterior Cervical Screw Spinal Fixation System (K000486) and the following other predicate devices:

Osteonics Anterior Cervical Compression Plating System, Line Extension – Howmedica Osteonics Corp. (K992344).
Osteonics Anterior Cervical Compression Plating System, Cortical Screws – Howmedica Osteonics Corp. (K993181).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2004

Ms. Joni L. Swoveland
Regulatory Affairs Assistant
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Re: K040017
Trade/Device Name: ABC Caudal and Cranial Extension Plate (e-Plate)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 5, 2004
Received: January 12, 2004

Dear Ms. Swoveland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040017

Device Name:

Indication for Use:

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Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109) (Optional Format 3-10-98)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040017